DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

REGISTRATION OF DEVICE ESTABLISHMENT

1. REGISTRATION NUMBER

2. OWNER/OPERATOR NUMBER

FORM APPROVED: OMB No. 0910-0387
EXPIRATION DATE: April 30, 2008

VALIDATION *(FDA USE ONLY)*

Submit an original copy.
Return form to *(this page only)*:
Food and Drug Administration
Center for Devices & Radiological Health, HFZ- 308
9200 Corporate Blvd.
Rockville, MD 20850-4015

3. TODAY'S DATE *(mm/dd/yyyy)*
05/12/05

4. TYPE OF REGISTRATION
☑ 4.1 Initial ☐ 4.2 Update ☐ 4.3 Preproduction

5. REQUIRED TO SUBMIT DEVICE LISTING *(Form FDA 2892)*?
☑ Yes ☐ No; If No, Explain:

6. REASON FOR UPDATE *(check all that apply)*
- ☐ 6.1 Establishment Name Change
- ☐ 6.2 Establishment Type Change *(deletion or addition)*
- ☐ 6.3 Establishment Address Change - Merged with Other Establishment
- ☐ 6.4 Establishment Address Change - Moved to New Location
- ☐ 6.5 Official Correspondent Name/Address Change
- ☐ 6.6 U.S. Agent Change
- ☐ 6.7 Owner/Operator Name/Address Change - Same Company New Name or Address
- ☐ 6.8 Owner/Operator Change - Sold Establishment
- ☐ 6.9 Out of Business
- ☐ 6.10 No Longer a Device Establishment
- ☐ 6.11 In Production
- ☐ 6.12 Trade Name or Establishment URL Change

7. Establishment Types *(check all that apply)*

Add	Delete	
☐	☐	7.1 Contract Manufacturer
☐	☐	7.2 Contract Sterilizer
☐	☐	7.3 Foreign Exporter
☐	☐	7.4 Initial Distributor/Importer
☑	☐	7.5 Manufacturer
☐	☐	7.6 Remanufacturer
☐	☐	7.7 Repackager/Relabeler
☐	☐	7.8 Reprocessor of Single Use Devices
☐	☐	7.9 Specification Developer
☐	☐	7.10 U.S. Manufacturer of Export Only Devices

8. ESTABLISHMENT ***(No P.O. Boxes)***
Business Name
Far East Medical Manufacturing

Number & Street
887 Main Blvd.

City: Hong Kong | State: | ZIP Code:

Foreign State: | Postal Code: HK4412 | Country: China

9. OFFICIAL CORRESPONDENT *(Name of Individual is required)*
Reason for OC Name Change *(see instructions)*:

Name
James Lee

Business Name
Far East Medical Manufacturing

Number & Street
123 Main Street

City: Bangkok | State: | ZIP Code:

Foreign State: | Postal Code: 3441 | Country: Thailand

9.1 EMAIL
jlee@fareast.com

9.2 PHONE NO. *(Phone no. should include area code or country/city codes)*
80-778-45889

9.3 FAX NO. *(Fax no. should include area code or country/city codes)*
80-778-45887

10. U.S. AGENT NAME AND ADDRESS
Same as Official Correspondent? ☐ Yes ☑ No
(If No, List Individual's Name, Title, Business Name, Number & Street, City, State, ZIP code.) **No P.O. Boxes. The U.S. Agent must either reside in the U.S. or maintain a place of business there.**

Name
Mr. Joseph Public

Title
Sr. Manager, Regulatory Affairs

Business Name
ABC Medical Device Distribution

Number & Street
123 Main Street

City: Anytown | State: MD | ZIP Code: 21703

10.1 EMAIL

10.2 PHONE NO. IN U.S. *(Phone no. should include area code)*
410-123-4567

10.3 FAX NO. IN U.S. *(Fax no. should include area code)*
410-123-5678

11. OWNER/OPERATOR ***(No P.O. Boxes)***
Business Name
Far East Medical Manufacturing

Number & Street
887 Main Blvd.

City: Bangkok | State: | ZIP Code:

Foreign State: | Postal Code: 3441 | Country: Thailand

11.1 PHONE NO. *(Phone no. should include area code or country/city codes)*

12. OTHER BUSINESS TRADING NAMES

13. SIGNATURE OF OFFICIAL CORRESPONDENT

13.1 PRINTED NAME *(Mr., Miss., Mrs., Ms., Dr.)*
Mr. James Lee

13.2 TITLE
Director, Quality Assurance

14. ESTABLISHMENT'S URL *(Optional)*:

NOTE: This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C.331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

FOR OFFICIAL USE ONLY
O / W / P / Y

FORM FDA 2891 (5/05) (PREVIOUS FORMS ARE OBSOLETE) **Note:** Validation of this form is not to be construed as FDA approval of the establishment or its products.

PSC Media Arts (301) 443-1090 EF

Instructions for Completing FDA Form 2891: Registration of Device Establishment - All information submitted must be in English. Submit a signed original copy.

Item 1. Registration Number - Fill in if a registration number has been previously assigned by the Food and Drug Administration (FDA). Leave this space blank if no registration number has been issued. FDA will assign a registration number after processing and provide this to the official correspondent.

Item 2. Owner/Operator Number - Fill in if an owner/operator Identification (I.D.) number has been previously issued by the FDA. Leave this space blank if no I.D. number has been issued. FDA will assign an I.D. number after processing and provide this to the official correspondent.

Item 3. Today's date - Enter the month, day, and year the form is completed using a MM/DD/YYYY date format.

Item 4. Type of registration:

4.1 Initial - Check this if it is the first time you are registering this establishment. If you are required to list, the initial registration form must be submitted with the initial listing form, and in the case of a foreign establishment, the United States agent information (Item #10). If the information is not submitted together, the initial registration form will not be accepted.

4.2 Update - Check this box if the form is being submitted to indicate changes in registration information that you have already submitted to the FDA. Only fill in the section/items that have changed and items 1 and 2.

4.3 Preproduction - Check this if you will not start producing medical devices for at least 3 months. You must notify FDA when you start producing medical devices. If the establishment does not notify the Center for Devices and Radiological Health (CDRH) that it has begun an activity that requires registration within 6 months, the preproduction registration form will then be archived without further processing. You are not officially registered until you have notified FDA of your active status.

Item 5. Required to Submit Listing - Check Yes or No. If No, explain why you are not required to list.

Who Must List - An owner/operator of an establishment not exempt under 21 CFR 807.65 who is engaged in the manufacture, preparation, propagation, compounding, assembly or processing of a medical device intended for commercial distribution (marketing) is required to list its device on form FDA 2892 within 30 days of entering the device into commercial distribution in the U.S. This includes manufacturers, repackagers and relabelers, specification developers, reprocessors of single-use devices, remanufacturers, foreign exporters and U.S. manufacturers of export only devices.

Domestic contract manufacturers and sterilizers that commercially distribute their devices must register and list their devices. Except in unique circumstances, initial distributors are the only establishment type not required to list.

Item 6. Reason for Update - Only fill this item out if type of registration is Update. Check all that apply.

6.1 Establishment Name Change - A change in the establishment name.

6.2 Establishment Type Change - A change in the types of activities which require registration as a medical device establishment (see Item 7 - Establishment Types).

6.3 Establishment Address Change - Merged with Other Establishment - Indicates establishment has merged with another establishment, and the new company is located at a different address from this registration.

6.4 Establishment Address Change - Moved to New Location - Change in the establishment address due only to a physical relocation.

6.5 Official Correspondent Name/Address Change - Any change in the Official Correspondent information, including name and address.

6.6 U.S. Agent Change - Any change in the US Agent information, including name and address.

6.7 Owner/Operator Name/Address Change - Same Company New Name or Address - Indicates only a new name and address for Owner/Operator, but establishment remains under same ownership.

6.8 Owner/Operator Change - Sold Establishment - Indicates Owner/Operator has changed because establishment sold to another firm.

6.9 Out of Business - The establishment has ceased to exist as an identifiable organization.

6.10 No Longer a Device Establishment - The establishment is no longer engaged in activities which require it to be registered as a medical device establishment, but the establishment is still in existence for other activities or purposes.

6.11 In Production - Notification that an establishment has gone from a "pre-production" status to an "in production" status.

6.12 Trade Name or Establishment URL Change - Any change in the Other Business Trading Names or the Establishment's URL.

Item 7. Establishment Types - You should only select the establishment types that apply to the operations performed at the establishment you are registering. Check all that apply to the establishment.

7.1 Contract Manufacturer - Manufactures a finished device to another establishment's specifications and puts device in commercial distribution.

7.2 Contract Sterilizer - Provides a sterilization service for another establishment's devices and puts the devices in commercial distribution.

7.3 Foreign Exporter - Exports or offers for export to the United States (U.S.), a device manufactured or processed by another individual, partnership, corporation or association in a foreign country, including devices originally manufactured in the United States. A foreign exporter must have an establishment address outside the U.S.

7.4 Initial Distributor/Importer - Takes first title to devices imported into the U.S. An Initial Distributor must have a U.S. address.

7.5 Manufacturer - Makes by chemical, physical, biological or other procedures, any article that meets the definition of "device" in Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

7.6 Remanufacturer - Processes, conditions, renovates, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or in any way changes the intended use.

7.7 Repackager - Packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding shipping containers).

Relabeler - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

7.8 Reprocessor of Single Use Devices - Performs remanufacturing operations on a single use device.

7.9 Specification Developer - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing operations on the device. This includes establishments that in addition to developing specifications also arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

7.10 U.S. Manufacturer of Export Only Devices - Manufactures medical devices that are not sold in the U.S. and are manufactured solely for export to foreign countries.

Item 8. Establishment Name and Address:

Name - Enter the legal name of the establishment conducting the regulated activity.

Address - Number and Street - Enter the number and street at which the registering establishment is located. Do NOT use postal box or rural route numbers.

Domestic Establishments:

City - Enter the city in which the establishment is located.

State - Enter the two-character state code of the U.S. Postal Service for the state, territory, or possession.

ZIP Code +4 - Enter the U.S. postal ZIP code +4 (if known).

Foreign Establishments:

Foreign State - Enter the foreign state (i.e., province, prefecture, region, territory) names in which the establishment is located.

Postal Code - Enter the foreign country postal code.

Foreign Country Name - Enter the full foreign country name.

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Instructions for Completing FDA Form 2891: Registration of Device Establishment - All information submitted must be in English. Submit a signed original copy.

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Item 9. Official Correspondent Name and Address:

Reason for OC Name Change - Briefly state why the OC Name is changing, e.g., OC left company, OC deceased, new owner had changed OC, OC moved onto new position in company.

Name - Enter the name of the individual designated as the official correspondent for registration and listing purposes.

Business Name - Enter the name of the establishment, owner or operator, or other place of business, with which the official correspondent is associated.

Address - Number and Street - Enter the number and street or post office box of the official correspondent's place of business. A post office box number is acceptable.

Domestic Correspondents:

City - Enter the city in which the official correspondent is located.

State - Enter the two-character state code of the U.S. Postal Service for the state, territory, or possession.

ZIP Code +4 - Enter the U.S. postal ZIP Code +4 (if known).

Foreign Correspondents:

Foreign State - Enter the foreign state (i.e., province, prefecture, region, territory) names in which the establishment is located.

Postal Code - Enter the foreign country postal code.

Foreign Country - Enter the full foreign country name.

9.1 Email - Enter the email address of the official correspondent (NO generic accounts, must be OC's own account).

9.2 Phone Number - Include country, city, area code, number and extension.

9.3 Fax Number - Include country, city, area code, and number.

Item 10. U.S. Agent Name and Address - The United States agent must either reside in the U.S. or maintain a place of business in the U.S. If the U.S. agent is also the Official Correspondent, check yes and you do not need to provide the address information but make sure that there is a U.S. phone and fax number. If the U.S. agent is a different person then check no and fill in the following information:

Individual's Name - Enter the name of the individual designated as the U.S. agent.

Agent's Title - Print/type the title of the U.S. agent.

Business Name - Enter the name of the place of business with which the U.S. agent is associated.

Number and Street - Enter the number and street of the U.S. agents's place of business. A post office box number is NOT acceptable.

City - Enter the city in which the U.S. agent is located.

State - Enter the two-character state code of the U.S. Postal Service for the state, territory, or possession.

ZIP Code +4 - Enter the U.S. postal ZIP Code +4 (if known).

10.1 Email - Enter the email address of the U.S. agent (NO generic accounts, must be Agent's own account).

10.2 Phone Number in U.S. - Include area code, number and extension. The United States agent cannot use an answering service or mail drop.

10.3 Fax Number in U.S. - Include area code, number and extension.

Item 11. Owner/Operator Name and Address:

Name - Enter the business name of the corporation, subsidiary, affiliated company, or partnership that is the owner or operator of the registering establishment. Only enter the proprietor's name or an individual's name if no other business name exists (abbreviate only if necessary).

Address - Number and Street - Enter the number and street at which the Owner/Operator is located. Do NOT use postal box or rural route numbers.

Domestic Owner/Operators:

City - Enter the city in which the owner/operator is located.

State - Enter the two-character state code of the U.S. Postal Service for the state, territory, or possession.

ZIP Code +4 - Enter the U.S. postal ZIP Code +4 (if known).

Foreign Owner/Operators:

Foreign State - Enter the foreign state (i.e., province, prefecture, region, territory) names in which the owner/operator is located.

Postal Code - Enter the foreign country postal code.

Foreign Country - Enter the full foreign country name.

11.1 Phone Number - Include country, city, area code, number and extension.

Item 12. Other Business Trading Names - Enter any other establishment names used. Please put a semi-colon between the names. Do not include the names of distributors for whom this establishment makes devices. Do not list registered trademarks in use by the firm.

Item 13. Signature of Official Correspondent - The signature of the designated official correspondent.

13.1 Name - Print/type the name of the official correspondent.

13.2 Title - Print/type the title of the official correspondent.

Item 14. Establishment's URL (Optional) - List the main web address associated with this establishment.

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015